UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: CHANTIX (VARENICLINE) MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION II	22-MD-3050 (KPF) 22-MC-3050 (KPF)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT PFIZER INC.'S MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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INTRODUCTION

This putative class action involves Pfizer's precautionary, voluntary recall of its smoking cessation medication Chantix. As Pfizer "offered a full rebate for any unused Chantix purchased by consumers . . . this lawsuit seeks damages for economic injury attributable to Chantix tablets that the plaintiffs consumed." *Harris v. Pfizer*, 586 F. Supp. 3d 231, 238 n.2 (S.D.N.Y. 2022). In *Harris*, Judge Denise Cote dismissed with prejudice the first-filed putative class action based on the same recall and nearly identical allegations. *Id.* at 237. This Court should do the same.

Cigarette smoking is the single most preventable cause of death in the United States. For that reason, medical organizations and government agencies universally agree the most important thing a smoker can do is to quit smoking. Yet, millions of smokers struggle to quit. Chantix, which contains the active ingredient varenicline, is a highly effective prescription medication "used to help consumers quit smoking." *Id.* When the U.S. Food and Drug Administration ("FDA") approved Chantix in 2006, it proclaimed that Chantix was a "significant potential benefit to public health." (*See* Ex. 1.)[1] The medicine also has a strong safety record with more than 15 years of real-world use globally. No medical, scientific, or regulatory body ever has suggested that Chantix could cause or increase the risk of cancer.

In 2018, the FDA began investigating the potential presence of nitrosamines in medicines. Nitrosamines are organic compounds common in water and foods, including cured and grilled meats, dairy products, and vegetables. Because nitrosamines are ubiquitous in the environment, nearly every human is exposed to some level of nitrosamines in their daily lives. Certain

[1] References to "Ex." are to exhibits accompanying the Declaration of Colleen Carey Gulliver, dated June 20, 2023. "[T]he Court may consider any statements or documents incorporated by reference in the complaint, documents that are 'integral' to the complaint even if they are not incorporated by reference, and matters of which judicial notice may be taken." *Blue Angel Realty, Inc. v. United States*, 2022 WL 94599, at *1 (S.D.N.Y. Jan. 8, 2022) (Failla, J.). "[C]ourts in the Second Circuit routinely take judicial notice of FDA documents." *Simeone v. T. Marzetti Co.*, 2023 WL 2665444, at *1-2 (S.D.N.Y. Mar. 28, 2023). Courts also have "taken judicial notice of facts from reputable medical sources such as the CDC." *Hall v. Annucci*, 2021 WL 4392526, at *1 (S.D.N.Y. Sept. 24, 2021).

nitrosamines—several of which are present in cigarettes—are classified as "possibly carcinogenic" (*i.e.*, substances that could cause cancer). *See Harris*, 586 F. Supp. 3d at 238.

The FDA has established acceptable daily intake ("ADI") limits for nitrosamines that extrapolate the amount a person could ingest every single day for her entire life (70 years) without increasing her theoretical cancer risk above 1 in 100,000. The Chantix label, in contrast, "recommends that most people take the medication for up to 12 weeks, with the possibility of another 12-week course." *Id.* at 237. Thus, the FDA's 70-year daily intake assumption does not reflect how Chantix is actually prescribed and used: for months, not decades.

Nonetheless, in July and August 2021, after testing of Chantix identified the presence of trace amounts of a newly-discovered nitrosamine called N-nitroso-varenicline ("NNV"), Pfizer voluntarily recalled certain lots of the product and offered patients reimbursement for any unused Chantix. In September 2021, Pfizer expanded the recall to include all Chantix lots and again offered patients reimbursement for any unused Chantix. (Ex. 2.) FDA informed patients that "there [was] no immediate risk to patients taking this medication" (*id*. at 2) and that "[t]here [was] no data available to directly evaluate the carcinogenic potential of [NNV]." (Ex. 3.) Thus, the decision to voluntarily recall Chantix was a precautionary measure, not based on evidence of any actual cancer risk associated with real-world use of the medication.

In the wake of this precautionary, voluntary recall, Roslyn Harris and Mary Allen, who "paid a co-pay for Chantix, and consumed at least some" of it, filed a complaint alleging the presence of NNV "rendered the product they paid for worthless." *Harris*, 586 F. Supp. at 238. The plaintiffs did not allege they "suffered any detriment to their health as a result" or "that Chantix failed to fulfill its purpose of helping its users to quit smoking." *Id.* at 238-39, 245. Instead, they alleged they "did not know that Chantix contained [NNV]," "did not see it listed as an ingredient

on the medication's box or labeling," and "would not have purchased the medication if they had known it was contaminated." *Id.* at 238. The plaintiffs asserted claims "grounded in contract and fraud," all of which Judge Cote dismissed with prejudice. *Id.* at 238-39.

Notwithstanding the *Harris* court's dismissal and the plaintiffs' decision not to appeal that ruling, 26 consumer plaintiffs (the "Consumer Plaintiffs"), including *Harris* plaintiff Mary Allen, and three third-party payors ("TPPs," and together with the Consumer Plaintiffs, "Plaintiffs") filed a Consolidated Class Action Complaint ("CAC") asserting nearly identical allegations and claims. Like the plaintiffs in *Harris*, Plaintiffs here "do not seek damages for any physical injuries" (CAC ¶ 255) and do not allege that Chantix failed to help patients quit smoking (*see id.* ¶¶ 24-46). Instead, like the *Harris* plaintiffs, Plaintiffs here allege that they were "economically harm[ed]" (*id.* ¶ 339; *see also id.* ¶¶ 20, 214), in that Chantix was "rendered worthless" by the presence of NNV (*id.* ¶ 10; *see also id.* ¶¶ 9, 24-46, 192, 197, 231, 254, 285).

Despite having more than a year to consider Judge Cote's *Harris* dismissal, the CAC is rife with vague and conclusory allegations and asserts ***identical legal theories and claims***, even on behalf of one of the ***same named plaintiffs***. Despite its length, at bottom this action is virtually identical to the case dismissed more than a year ago by Judge Cote, and suffers from the same deficiencies (and more), including that:

(1) Plaintiffs have not pled actionable misrepresentations or omissions by Pfizer because Plaintiffs assert the same purported fraudulent statements rejected by Judge Cote and have not plausibly alleged facts in support of the alleged misrepresentations or omissions;

(2) Plaintiffs have not pled a compensable injury because (a) they do not allege that Chantix failed to assist patients to quit smoking, (b) they do not allege that NNV caused patients physical

harm, and (c) no cheaper alternatives were available to plausibly assert a price premium caused by a failure to disclose the presence of NNV;

(3) Plaintiffs' claims are impliedly preempted by federal law;

(4) Plaintiffs' tort claims are barred by the economic loss doctrine;

(5) Plaintiffs lack standing to assert a nationwide class or seek injunctive relief;

(6) *res judicata* bars Plaintiff Mary Allen's claims; and

(7) certain of Plaintiffs' individual claims fail for other reasons as well, as set forth below.

Thus, like *Harris*, the CAC should be dismissed in its entirety and with prejudice.

BACKGROUND[2]

A. Cigarette Smoking Causes Cancer and Quitting is Difficult.

Cigarette smoking is the single most preventable cause of death in the United States. (Ex. 1.) Each year, cigarette smoking causes more than 480,000 deaths in the U.S.—about one in every five deaths. (Ex. 4 at 1.) Cigarettes contain over "70 chemicals"—including "tobacco-specific nitrosamines"—that can cause diseases including "cancer, heart disease . . . and chronic obstructive pulmonary disease." (Ex. 5 at 2; Ex. 6.) Overall, one in three cancer deaths is caused by smoking (Ex. 7 at 2), and, on average, smokers die 10 years earlier than nonsmokers. (Ex. 6.) Quitting smoking significantly decreases an individual's risk of cancer:

- "Within 5-10 years of quitting, your chance of getting cancer of the mouth, throat, esophagus, or voice box drops by half" (Ex. 8 at 2)
- "Within 10-15 years after you quit smoking, your risk of lung cancer drops by half." (*Id.*)
- If nobody smoked, "one of every three cancer deaths" in the United States would not happen. (Ex. 7 at 2.)

[2] Pfizer assumes the factual allegations in the CAC are true only for purposes of this motion, unless they are contradicted by other allegations, documents referenced in the CAC, or judicially noticeable facts.

While nearly 7 in 10 adult cigarette smokers want to stop smoking, less than 8% are successful. (Ex. 7 at 2.) It is a "very difficult" habit to break because nicotine, the active ingredient in cigarettes, is highly addictive. (Ex. 1 at 1.) The high relapse rate also is attributable to a failure to use proven smoking cessation interventions, such as Chantix. (Ex. 9 at 24.)

B. FDA Employs a Rigorous Approval Process for Medications.

The Food, Drug, and Cosmetic Act ("FDCA") "regulates the manufacture, use, or sale of drugs." *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 176 (S.D.N.Y. 2016). "[T]o obtain authorization to market a new drug, a drugmaker must submit a new drug application ('NDA')." *Id.* at 177. The NDA must "include 'full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.'" *Id.* Before receiving approval, Pfizer had to prove Chantix was "safe for use under the conditions prescribed" in the proposed labeling, provide "substantial evidence" it would "have the effect it purports," and identify its specific composition, including inactive ingredients added to the medication (known as excipients). *See id.*; *see also* 21 U.S.C. 355(b)(1). "The FDA's premarket approval of an NDA includes the approval of the exact text in the proposed label." *Utts*, 226 F. Supp. 3d at 177.

C. Chantix is Safe and Effective.

On May 11, 2006, after finding Chantix had "significant potential benefit to public health," FDA approved the medication as the first new smoking cessation treatment to enter the U.S. market in more than a decade. (Ex. 1 at 1.) Chantix is intended for short-term use only. As stated on the label, Chantix is designed to be taken for 12 or 24 weeks total. (Ex. 10 at 21; Ex. 11 at 1.) The CDC explained that Chantix is "***much safer*** than smoking . . . . If you keep smoking instead, you will be exposed to the hundreds of toxic chemicals in cigarette smoke," and quit-smoking pills are used for a short time compared to continuing to smoke. (Ex. 12 (emphasis added).) Chantix has a "long track record" of demonstrated efficacy and "safe[ty]." (*Id.*) Chantix has been the subject

of extensive clinical studies in more than 200,000 smokers in the past fifteen years. (Ex. 13.)

D. FDA's Investigation of Nitrosamines and Establishment of ADIs.

A nitrosamine is "a chemical compound classified as *possibly* carcinogenic." *Harris*, 586 F. Supp. 3d at 238 (emphasis added). "Everyone is exposed to some level of nitrosamines," as they are "common in water and foods." (Ex. 14 at 4.) While nitrosamines are ubiquitous in the environment, FDA did not anticipate that nitrosamines could be present in medicines. (Ex. 15 at 1.) In September 2020, FDA published a non-binding Nitrosamine Guidance document ("Nitrosamine Guidance") for industry, which it updated in February 2021 in response to "the recent unexpected finding of nitrosamine impurities" in other companies' medicines. *Id.* at 1-3.) The Nitrosamine Guidance recommends that pharmaceutical manufacturers take steps to detect and prevent unacceptable levels of nitrosamines. (*Id.* at 1.) By February 2021, FDA had identified seven potential nitrosamines (not including NNV) that theoretically could be present in medicines. (Ex. 15 at 4.)

FDA also published ADIs for certain nitrosamines, which represent the daily intake level that, if consumed every day for a period of ***70 years***, could create a theoretical lifetime cancer risk of 1 in 100,000. (*Id.* at App'x B.) A series of conservative assumptions inform FDA's ADI calculations; for example, FDA uses the most conservative carcinogenicity data available, if any, for the specific nitrosamine at issue and assumes that the exposed person weighs approximately only 110 pounds and will take the medicine daily for 70 years. (*Id.*) Because of these assumptions, FDA acknowledges that "[a] drug product intended for only short-term use . . . poses ***less risk*** than a drug product intended for chronic use." (*Id.* at 9 n.30 (emphasis added).) The ADI calculation also considers the amount of the specific nitrosamine that results in a 50% tumor incidence rate in the laboratory animal most sensitive to that nitrosamine, a value called the TD_{50}. (*Id.* at App'x B.)

E. The Discovery of NNV in Chantix and Pfizer's Voluntary Recall.

Beginning in July 2021, Pfizer voluntarily recalled certain Chantix lots as a precautionary measure due to the discovery of trace amounts of NNV. (Ex. 3; *see* CAC ¶¶ 14-16.) Because NNV was not previously known, there was "no data available to directly evaluate [its] carcinogenic potential" and establish a TD_{50}, and, thus, FDA had not yet established an ADI. (Ex. 3; *see also* Ex. 15 at App'x B.) Instead, FDA used "information available on closely related nitrosamine compounds . . . to calculate lifetime exposure limits" for NNV. (Ex. 3.) Based on its conservative assumptions, FDA calculated an ADI for NNV of 37 ng / day. (Ex. 20; *see also* Ex. 15, at App'x B.) Thus, FDA assumes a 110-pound female who consumed 37 ng of NNV ***every day for 70 years*** would have a theoretical (albeit unproven) 1 in 100,000 chance of developing cancer. By contrast, smoking causes one in three cancer deaths every year. (Ex. 7 at 2.)

At the time of Pfizer's voluntary recall, FDA informed patients that "***there is no immediate risk to patients taking [Chantix]***" because, while NNV "may be associated with a potential increased cancer risk in humans," there "are ***no data available to directly evaluate the carcinogenic potential of [NNV]***." (Ex. 3 at 1 (emphasis added).) FDA classified the recall as Class II, which means that "the probability of serious adverse health consequences is remote." (Exs. 21, 16.) While nitrosamine "impurities may increase the risk of cancer if people are exposed to them above acceptable levels ***over long periods of time***," Chantix is intended for short-term use only. (Ex. 2 (emphasis added).) As such, FDA "urged patients to continue taking the drug even after the recall." *Harris*, 586 F. Supp. 3d at 245. And, due to the obviously overwhelming cancer risk from smoking, FDA explained that "***the health benefits of stopping smoking outweigh the cancer risk from the nitrosamine***" in Chantix. (Ex. 3 at 1 (emphasis added).)

F. Possible Causes of Nitrosamines in Medicines.

Two months later, in November 2021, FDA announced "possible mitigation strategies to

reduce the risk of nitrosamine drug substance-related impurities" ("NDSRIs"). (Ex. 17 at 1.) FDA explained it had received "additional reports of certain types of nitrosamine impurities that formed in several drug products" and concluded these NDSRIs were occurring due to one of three causes:

> NDSRIs can be generated during manufacturing or during the shelf-life storage period of the drug product. In some cases, the root cause of NDSRI formation has been attributed to nitrite impurities present in excipients at parts-per-million amounts. Nitrite impurities have been observed in a range of commonly used excipients (as well as water) and may lead to the formation of NDSRIs in certain drug products. (*Id.*)

G. The Key Allegations in *Harris* and This MDL Are the Same.

On the heels of Pfizer's voluntary recall, plaintiff Roslyn Harris filed *Harris*, the first putative class action. *See* 586 F. Supp. 3d at 237-39. In February 2022, Judge Cote granted Pfizer's motion to dismiss the case with prejudice—a decision Harris and Allen did not appeal. Over the next few months, Plaintiffs largely represented by the same counsel filed 19 more cases, which ultimately were coordinated in this MDL.

In the CAC, the Consumer Plaintiffs, who are residents of only 12 states, seek to represent a nationwide class of Chantix users. (*See* CAC ¶¶ 24-46, 205.) They fail to allege with any specificity their purported Chantix purchases, including the date of their purchases; how many times they purchased Chantix; or the amount they paid (even though Ms. Allen included some of that information in her amended *Harris* complaint, *see* 586 F. Supp. 3d at 238). The three named TPPs—County of Monmouth, MSP Recovery Claims Series 44, LLC ("MSP"), and Ohio Carpenters' Health Fund, which are located in New Jersey, Florida, and Michigan, respectively—allege they or their assignors are "responsible for reimbursing or paying for beneficiaries' purchases" and that they "paid more for [Chantix] than [they] would have absent [Pfizer's]

misconduct." (CAC ¶¶ 47-48, 50, 72, 74-75.)[3] The TPPs allege that they or their assignors "purchased or paid" for Chantix for beneficiaries in 35 jurisdictions and seek to represent a nationwide class of TPPs who paid for Chantix. (*Id.* ¶¶ 48, 72, 75, 205-06.)

The key allegations from *Harris* are repeated in the CAC (emphasis added below):

Harris	***CAC***
Plaintiffs ***did not "allege[]*** that they ha[d] suffered any detriment to their health" or "that they have suffered any emotional or ***physical injury*** from taking Chantix." *Harris*, 586 F. Supp. 3d at 238-39.	"Plaintiffs and other Class Members ***do not seek damages for any physical injuries***." (CAC ¶ 255; *see also id.* ¶¶ 232, 331.)
Plaintiffs "***do not allege*** that Chantix ***failed to fulfill its purpose*** of helping its users to quit smoking." *Harris*, 586 F. Supp. 3d at 245.	***No allegations*** that consumed Chantix ***did not help*** patients quit smoking. *See generally* CAC.
"Plaintiffs seek damages solely for their ***economic injury***." *Harris*, 586 F. Supp. 3d at 238.	"Defendant's misrepresentations and omissions . . . ***economically harm[ed]*** . . . Plaintiffs." (CAC ¶ 339; *see also id.* ¶¶ 20, 214.)
"The plaintiffs complain that the presence of [NNV] rendered the product . . . ***worthless***." *Harris*, 586 F. Supp. 3d at 238.	Chantix "w[as] adulterated, misbranded, or both (and thereby rendered ***worthless***, or alternatively, certainly worth less)." (CAC ¶ 10; *see also id.* ¶¶ 9, 24-46, 192, 197, 231, 254, 285.)
"[T]he plaintiffs allege that they ***did not know*** that Chantix contained [NNV], that they did not see it listed as an ingredient on the medication's box or labeling." *Harris*, 586 F. Supp. 3d at 238.	"Because Pfizer ***did not disclose*** that its VCDs contained [NNV] . . . the subject drugs were misbranded." (CAC ¶ 149; *see also id.* ¶¶ 221, 231, 241, 294.)
Pfizer misrepresented "that the product [Plaintiffs] purchased was ***'Chantix,' as approved by the FDA***." *Harris*, 586 F. Supp. 3d at 240.	Pfizer misrepresented that Chantix was "the ***same as, the actual FDA-approved brand name drug Chantix***." (CAC ¶ 7; *see also id.* ¶¶ 85, 150, 192, 219.)
Pfizer misrepresented that "[Chantix] ***contained only the active ingredient varenicline***." *Harris*, 586 F. Supp. 3d at 240.	Pfizer misrepresented "Chantix's . . . ***active and inactive ingredients***." (CAC ¶ 116; *see also id.* ¶¶ 141, 192.)

LEGAL STANDARD

Under Rule 12(b)(6), a complaint must be dismissed if it does not "contain sufficient

[3] MSP alleges that it has been assigned rights to recover payments made by "[c]ertain Medicare Advantage plans and healthcare benefit providers." (CAC ¶ 52.)

factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Though the Court must accept factual allegations as true, 'mere conclusory statements' and legal conclusions 'are not entitled to the assumption of truth.'" *Freeman v. Kirisits*, 818 F. App'x 34, 38 (2d Cir. 2020) (quoting *Iqbal*, 556 U.S. at 678-79)). In addition, "[a] party alleging fraud must 'state with particularity the circumstances constituting fraud.'" *Harris*, 586 F. Supp. 3d at 240 (quoting Fed. R. Civ. P. 9(b)).

ARGUMENT

I. PLAINTIFFS HAVE NOT ALLEGED ANY PLAUSIBLE MISSTATEMENT OR DECEPTIVE OMISSION.

To state a claim under the various states' consumer protection statutes, as well as under their common law fraud-based counterparts, a plaintiff must allege that a defendant made a materially misleading statement that is likely to mislead a "reasonable consumer." *Dwyer v. Allbirds, Inc.*, 598 F. Supp. 3d 137, 154 (S.D.N.Y. 2022). A defendant does not commit such a deceptive act "by simply publishing truthful information and allowing consumers to make their own assumptions about the nature of the information." *Id.* at 150 (citation omitted). "[I]t is 'well settled that a court may determine as a matter of law that an allegedly deceptive [advertisement] would not have misled a reasonable consumer.'" *Id.* at 149.

Judge Cote held that the *Harris* plaintiffs failed "to plausibly allege that Pfizer represented or warranted that their product was free of nitrosamines—or . . . that Pfizer had a duty to disclose any nitrosamine contamination." 586 F. Supp. 3d at 239. The CAC suffers from the same defects.

A. Plaintiffs Have Not Plausibly Pled Any Misstatement by Pfizer.

"[T]he determinative issue is whether Plaintiff has set forth enough facts to support the contention that the alleged deceptive act or practice plausibly could have occurred." *Woods v. Maytag Co.*, 2010 WL 4314313, at *15 (E.D.N.Y. Nov. 2, 2010). Plaintiffs assert that Pfizer made

three misstatements: that Chantix (1) was the "same as FDA-approved Chantix" ("the sameness misstatement") (CAC ¶¶ 265-66; *see also id.* ¶¶ 7, 24-46, 330); (2) contained only varenicline as the active ingredient ("the active ingredient misstatement") (*id.* ¶¶ 265-66, 226; *see also id.* ¶¶ 24-46, 336); and (3) was manufactured in compliance with current Good Manufacturing Practices ("cGMP") regulations ("the cGMP misstatement") (*id.* ¶¶ 265-66; *see also id.* ¶¶ 24-46, 191, 336). The CAC fails to state a claim with respect to any of these purported misstatements.

As a threshold matter, Plaintiffs do not identify any document in which Pfizer made these purported misstatements, other than the Chantix label. Instead, they vaguely assert that Pfizer made the misrepresentations through unspecified "marketing or informational materials," "brochures," and "websites." (*Id.* ¶ 191.) But "general references to advertisements and statements will not be sufficient to allege a deceptive act or practice," *Woods*, 2010 WL 4314313, at *16, let alone to satisfy the "heightened pleading standard" applicable to Plaintiffs' fraud-based claims. *See, e.g.*, *Harris*, 586 F. Supp. 3d at 240-43; *Zottola v. Eisai Inc.*, 564 F. Supp. 3d 302, 312 (S.D.N.Y. 2021) (dismissing consumer protection claims because plaintiffs alleged only "unspecified misleading representations contained in the Medications' 'labels and disclosures'"); *Dains v. Bayer Healthcare LLC*, 2022 WL 16572021, at *6 (N.D.N.Y. Nov. 1, 2022) (dismissing "vague allegations" of safety risks because plaintiff did not provide details of "precise statements that were made, by whom, or when"); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 682-83 (S.D.N.Y. 2017) (dismissing California consumer protection claims "premised on allegations of fraudulent conduct" under Rule 9(b)). All of Plaintiffs' claims fail for this lack of particularity alone.

Plaintiffs' claims also fail because they have not alleged any actionable misstatement.

Sameness Misstatement. First, with respect to the alleged sameness misstatement, Judge Cote already held in *Harris* that the "presence of a contaminant does not render the brand name on the label false" because "contaminated Chantix is still Chantix," a holding equally applicable here. *See* 586 F. Supp. 3d at 241; *see also Axon v. Florida's Nat. Growers,* 813 Fed. App'x 701, 705 (2d Cir. 2020) (affirming dismissal of false advertising claims involving an alleged contaminant because a reasonable consumer "would not make assumptions regarding the presence or absence of trace amounts" of a contaminant). Plaintiffs allege that the Chantix they purchased was not "bioequivalent" and that the supposed cGMP violations "rendered the product[] . . . misbranded" and different from the "FDA-approved brand name drug Chantix." (CAC ¶¶ 7-9.) But Plaintiffs do not plead "enough facts to 'nudge'" their "claims across the line from conceivable to plausible'" as they allege no facts to suggest that the NNV in Chantix made it different from what FDA approved. *See U.S. Cap. Partners, LLC v. Stanwich Cap. Advisors, LLC,* 2015 WL 4388421, at *2 (S.D.N.Y. July 17, 2015) (Failla, J.). Instead, they speculate that, because generics launched after Pfizer's recall contained lower levels of NNV, the Chantix Pfizer sold Plaintiffs must have differed from the Chantix FDA originally approved due to cGMP violations, akin to a *res ipsa loquitur* inference. (*See* CAC ¶ 17.) "This inferential leap is entirely unjustified," particularly here, where FDA has stated that there are multiple potential causes for nitrosamines. *See Campbell v. Drink Daily Greens, LLC*, 2018 WL 4259978, at *5 (E.D.N.Y. Sept. 4, 2018).

Active Ingredient Misstatement. Second, Judge Cote also considered and squarely rejected Plaintiffs' contention that Pfizer represented that Chantix contained "only varenicline as the active ingredient" in holding that "neither [Chantix's] product label nor the medication guide state that varenicline is the *only* biologically active ingredient in Chantix." *Harris*, 586 F. Supp. 3d at 241. Further, Plaintiffs, as they did in *Harris*, specifically "disclaim any attempt to privately

enforce the FDA's limits on nitrosamine contamination." 586 F. Supp. 3d at 239; *see* CAC ¶ 133. And to the extent Plaintiffs now seek to rely on FDA regulations pertaining to active ingredients as a basis for their complaint, such claims are also preempted. *See infra* Part III.C.

cGMP Misstatement. Finally, Plaintiffs also have not plausibly pled that Pfizer failed to comply with cGMP regulations, and thus that any statement was false. The FDA has informed the public that "[t]here are multiple reasons why nitrosamines can be present in drugs." (*See* Ex. 14 at 7.) While Plaintiffs conjecture that the presence of a nitrosamine means that Pfizer failed to comply with cGMPs (*see* CAC ¶ 17), "[c]ourts have consistently held that mere speculation is insufficient." *MECO Elec. Co. v. Siemens Indus., Inc.*, 2022 WL 4085832, at *8 (S.D.N.Y. Sept. 6, 2022); *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, at 555 (2007) ("Factual allegations must be enough to raise a right to relief above the speculative level"). No factual support is provided by an unrelated March 2015 FDA warning letter issued to a different pharmaceutical company based on inspections in 2014 at an Italian facility that Pfizer did not acquire until September 2015—six months ***after*** the warning letter. (CAC ¶ 183 (quoting Ex. 18); *see also* Ex. 19). Purported violations of cGMP regulations at a facility Pfizer did not own (and thus where Chantix was not manufactured at the time) are irrelevant, and "the Second Circuit has expressly rejected this sort of 'if it happened there, it could have happened here' reasoning." *See In re Mexican Gov't Bonds Antitrust Litig.*, 412 F. Supp. 3d 380, 391 (S.D.N.Y. 2019). By contrast, in *Valsartan*, the FDA conducted "inspections of . . . ***Defendants'*** facilities" and issued warning letters to defendants about the presence of nitrosamine at that location. *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 100204, at *2 (D.N.J. Jan. 12, 2021) (emphasis added).

B. Plaintiffs Have Not Plausibly Alleged that Pfizer Had a Duty to Disclose the Presence of NNV.

"In cases alleging a deceptive act based on an omission, it is not sufficient for a plaintiff to point solely to the omission." *Dimond v. Darden Rests.*, 2014 WL 3377105, at *13 (S.D.N.Y. July 9, 2014) (Failla, J.). Instead, there must be a duty to disclose, which will generally arise "only when '(1) one party makes a partial or ambiguous statement that requires additional disclosure to avoid misleading the other party, or (2) one party possesses superior knowledge, not readily available to the other, and knows that the other is acting on the basis of mistaken knowledge.'" *Harris*, 586 F. Supp. 3d at 241. A claim for negligence demands likewise. *Phoenix Cos. v. Concentrix Ins. Admin. Sols. Corp.*, 554 F. Supp. 3d 568, 589 (S.D.N.Y. 2021) (Failla, J.) (negligence requires a duty).[4] As in *Harris*, Plaintiffs here "have not plausibly alleged a duty," which dooms Plaintiffs' omission and negligence-based claims. *See* 586 F. Supp. 3d at 241.

First, Plaintiffs fail to "identify a partial statement by Pfizer that was rendered false or misleading by any omission." *Harris*, 586 F. Supp. 3d at 241. While Plaintiffs suggest, as they did in *Harris*, that "Chantix's product and active ingredient labels are misleading because they do not disclose the presence of a nitrosamine contaminant," that "omission does not render either the brand name 'Chantix' or the active ingredient label 'varenicline' false or misleading." *Id.* at 241-42; *see supra* Part I.A. "Courts in several states," including certain of those at issue here, "have held that a defendant's failure to disclose that its product contains trace amounts of carcinogens

[4] In an attempt to plead a duty, Plaintiffs assert negligence per se claims, alleging that "federal cGMPs and federal adulteration standards as incorporated by state law . . . created independent state-law duties." (CAC ¶¶ 373-74.) But courts in New York and elsewhere have rejected the use of negligence per se as applied to "vague and open-ended" cGMPs because they do not impose specific duties. *Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 218 (E.D.N.Y. 2017); *see also Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 587-88 (E.D.N.Y. 2009) (dismissing negligence per se claim because cGMPs "are intended to serve only as 'an umbrella quality system' providing 'general objectives'" and "cannot serve as the basis for a parallel claim"); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 699 (W.D. Tenn. 2011) ("The CGMP regulations cited by Plaintiffs govern a manufacturer's general practices . . . They cannot support a negligence per se claim and, likewise, a parallel claim").

does not violate state-law duties." *In re: Zantac (Ranitidine) Prods. Liab. Litig.*, 2023 WL 2817576, at *10 (S.D. Fla. Apr. 6, 2023) (collecting cases); *see also In re: General Mills Glyphosate Litig.*, 2017 WL 2983877, at *6 (D. Minn. July 12, 2017); *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 979-80 (S.D. Ohio 1992), *aff'd*, 24 F.3d 809 (6th Cir. 1994).[5]

Second, as Judge Cote held, Plaintiffs have not plausibly alleged that "the contamination was material to the plaintiffs." *Harris*, 586 F. Supp. 3d at 241. Nor can they. "An omission is materially misleading . . . where the plaintiff would have acted differently had the defendant disclosed the information in its possession." *Braynina v. TJX Cos., Inc.*, 2016 WL 5374134, at *5 (S.D.N.Y. Sept. 26, 2016). However, it is facially implausible that smokers facing health effects of long-term use of tobacco—which itself contains far more tobacco-specific nitrosamines and cancer-causing chemicals—would forego taking Chantix for a short period of time where, as FDA found, "[t]he health benefits of stopping smoking outweigh" the theoretical "increased cancer risk . . . associated with long-term use" (Ex. 3 at 1). *See Iqbal*, 556 U.S. at 679 ("Determining whether a complaint states a plausible claim . . . requires the reviewing court to draw on its judicial experience and common sense.").

Third, Plaintiffs have not plausibly alleged that Pfizer had knowledge of NNV ***at the time of their purchases***. Consumer Plaintiffs have not even pled when they made their purchases (*see*

[5] The learned intermediary doctrine, which provides that a "prescription drug manufacturer's 'duty to warn extends only to members of the medical profession and not to the consumer,'" also requires dismissal. *McElroy v. Eli Lilly & Co.*, 495 F. App'x 166, 168 (2d Cir. 2012); *see also Batchelor v. Pfizer, Inc.*, 2013 WL 3873242, *2 (M.D. Ala. July 25, 2013) ("Defendant had no duty to warn Plaintiff, only to warn her physicians adequately and honestly, and Plaintiff offers no factual allegations to support the theory that there was an inadequate or dishonest warning."). Indeed, the FDA "remind[ed]" patients "to continue taking [Chantix] until your doctor or pharmacist gives you a replacement or ***different treatment option.***" (Ex. 3 at 1) (emphasis added). Because Plaintiffs do not allege that their physicians "would have altered their prescription decisions if [Pfizer] had provided different warnings," *McElroy*, 495 F. App'x at 168, they fail to overcome "the well-established learned intermediary doctrine." *See In re Zyprexa Prod. Liab.*, 2009 WL 1514427, at *13 (E.D.N.Y. May 29, 2009); *see also Fearrington v. Bos. Sci. Corp.*, 410 F. Supp. 3d 794, 801 (S.D. Tex. 2019) (granting motion to dismiss where plaintiffs failed to "plead facts that would show . . . her doctors would have recommended different treatment" and explaining the "learned intermediary doctrine is not an affirmative defense but part of the case Plaintiff must prove to establish Defendant violated an owed duty").

CAC ¶¶ 22-46; *see also infra* Part II.A) and thus it is impossible for the Court to infer that Pfizer had knowledge of NNV at the time. In any event, the CAC alleges only that Pfizer should have started to investigate whether Chantix contained a potential nitrosamine sometime after October 2020, when "Health Canada asked all companies marketing a varenicline product . . . to evaluate and test their products for nitrosamines." (CAC ¶¶ 13, 169.) As Judge Cote held, "[t]hese allegations . . . at most only show that Pfizer ***may*** have known that its medication was ***at risk*** of contamination by late 2020. They do not show that Pfizer knew or believed that Chantix was actually contaminated, particularly when the plaintiffs purchased Chantix." *Harris*, 586 F. Supp. 3d at 241 (emphasis added). By February 2021, FDA had not yet identified NNV as one of the seven known nitrosamines found in medications. (Ex. 15 at 4.) Yet Pfizer was able to investigate the presence of a novel nitrosamine and coordinate a voluntary recall in a matter of months. (*See* Ex. 2.) Finally, the alleged presence of ***other*** nitrosamines ***in other medications*** in July 2018 (*see, e.g.*, CAC ¶¶ 299; 168, 176-77, 320, 352) does not demonstrate that Pfizer had knowledge of a potential nitrosamine in Chantix. Thus, Plaintiffs have not pled an actionable omission.

II. PLAINTIFFS HAVE NOT PLED A COMPENSABLE INJURY.

Each of Plaintiffs' claims suffers from another fundamental defect—failure to allege injury. Plaintiffs have failed to allege a cognizable injury because: (1) the Consumer Plaintiffs have not adequately alleged their purchases; (2) Plaintiffs received the benefit of their bargain; (3) Plaintiffs cannot proceed on a theory that Chantix is worthless; and (4) a price premium theory is implausible.[6]

A. Consumer Plaintiffs Have Not Adequately Alleged Their Chantix Purchases.

The Consumer Plaintiffs' conclusory allegations of Chantix purchases are insufficient to

[6] Pfizer moved to dismiss for a lack of injury necessary to state a claim in *Harris*, which was not addressed by Judge Cote, as the court held the complaint failed to state a claim for other reasons. *See* 586 F. Supp. 3d at 239.

establish a concrete and plausible injury. "A plaintiff may not 'rely solely on conclusory allegations of injury.'" *Calcano v. Swarovski N. Am. Ltd.*, 36 F.4th 68, 76 (2d Cir. 2022). For example, in *Wilson v. Mastercard Inc.*, the court held that the plaintiff had not plausibly pled a "financial injury" because she did not allege "how much she was overcharged," the "date the transaction occurred," or "the amount . . . of the item that she purchased." 2022 WL 3159305, at *4-5 (S.D.N.Y. Aug. 8, 2022). The court explained that "[w]hile courts 'generally accept the truth of a plaintiff's allegations' at the pleading stage, they 'need not credit a naked assertion devoid of further factual enhancement.'" *Id.* at *4 (quoting *Calcano*, 36 F.4th at 75). Similarly, in *Colella v. Atkins Nutritionals, Inc.*, the court held that the plaintiff in a false advertising putative class action had "failed to adequately plead injury" because "[he] provide[d] limited detail regarding [his] purchases" and "fail[ed] to allege with specificity where he purchased the products, when he purchased the products, or what he paid." 348 F. Supp. 3d 120, 142-43 (E.D.N.Y. 2018).

The same result is compelled here. All Consumer Plaintiffs baldly allege that on some unspecified date during an undefined "class period," they purchased Chantix. (*See* CAC ¶¶ 24-46.) They do not provide the date of the purchase, whether they purchased Chantix more than once, or what they paid for the prescription. (*See id.*) These vague allegations are insufficient to plead a concrete and plausible injury.[7]

B. Plaintiffs Received the Benefit of Their Bargain.

Plaintiffs here do not plausibly allege that they failed to receive the benefit of their bargain because they have not alleged that Chantix failed to work as intended and have not plausibly

[7] Plaintiffs' generalized allegations do not even permit Pfizer to determine whether it has statutes of limitations defenses to any of Plaintiffs' many claims. Because Plaintiffs only have alleged a purchase "during the class period," which is undefined (*see* CAC ¶¶ 24-46), Pfizer is unable to properly assess its defenses. *See Boyer v. Channel 13, Inc.*, 2005 WL 2249782, at *7 (S.D.N.Y. Mar. 9, 2005) (dismissing claim where plaintiff failed to "define[] the market with sufficient specificity to provide the defendants with fair notice of his claims" and noting failure to allege scope "severely hampers [defendants'] ability to answer the Amended Class Action complaint").

alleged that Chantix was unsafe.

1. Plaintiffs Have Not Alleged That Chantix Failed to Work as Intended.

A plaintiff suffers no economic injury if they "paid for an effective [product], and . . . received just that—the benefit of [their] bargain." *Rivera v. Wyeth-Ayerst Labs*, 283 F.3d 315, 320 (5th Cir. 2002); *accord Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 176 (D.D.C. 2003) ("Those patients who purchased [the medication] . . . and who obtained effective pain relief . . .received the 'benefit of their bargain.'"); *Baron v. Pfizer, Inc.*, 42 A.D.3d 627, 629 (N.Y. App. Div. 2007) (affirming lack of injury and noting that "plaintiff failed even to allege . . . that [medication] was ineffective"). In their 381-paragraph CAC, Plaintiffs, just like the *Harris* plaintiffs, do not allege that "Chantix failed to fulfill its purpose of helping its users to quit smoking." *Harris*, 586 F. Supp. 3d at 245. Because these patients "consumed" smoking cessation medication that worked as intended (*see* CAC ¶ 19), they received the benefit of their bargain.

2. Plaintiffs Have Not Plausibly Pled That Chantix Is Unsafe.

Plaintiffs similarly do not plausibly allege a substantially certain risk of future physical harm to patients from taking Chantix. A plaintiff who claims "that she did not receive the full value of her purchase" due to a product safety concern must "plausibly allege that the [product] is harmful." *Housey v. Procter & Gamble Co.*, 2022 WL 874731, at *9 (S.D.N.Y. Mar. 24, 2022), *aff'd*, 2022 WL 17844403 (2d Cir. Dec. 22, 2022). To state a claim, "Plaintiffs must plead a credible or substantial threat to their health." *In re Gerber Prod. Co. Heavy Metals Baby Food Litig.*, 2022 WL 10197651, at *5 (E.D. Va. Oct. 17, 2022). "[F]ear and apprehension about a possible future physical or medical consequence . . . is not enough." *Id.*

In *Housey*, for example, the court dismissed false advertising claims alleging that the presence of charcoal in the defendant's toothpaste was "harmful." 2022 WL 874731, at *9. The court explained that an economic injury requires the plaintiff to plausibly plead that the product

was actually harmful, and plaintiff had not demonstrated that the product contained sufficient charcoal to be unsafe. *Id*. The Second Circuit affirmed because the plaintiff's complaint failed to allege the toothpaste contained enough charcoal to be harmful. *See* 2022 WL 17844403, at *2.

Moreover, in evaluating whether plaintiffs have plausibly alleged that a product can cause harm, courts have repeatedly "declined to find injury" where FDA issued statements "indicat[ing] that the products at issue were safe." *Kimca v. Sprout Foods, Inc.*, 2022 WL 1213488, at *7 (D.N.J. Apr. 25, 2022). In *Kimca*, plaintiffs sought to recover for economic injuries allegedly caused by the presence of purportedly toxic heavy metals in the defendant's baby food. *Id*. There, the FDA had informed the public that "at the levels we have found through our testing . . . children ***are not at an immediate health risk***." *Id.* (emphasis added). The court concluded that such a pronouncement "[a]t the very least . . . weakens the inference that the amount of heavy metals in the Baby Food Products creates a substantial risk of danger to children." *Id.*

Such is the case here. Plaintiffs repeatedly include the threadbare allegation that NNV "can cause cancer" such that this exposure "implicat[es] potential health consequences." (CAC ¶¶ 139, 255; *see also id.* ¶¶ 171, 197, 379.) But the FDA explained that "***there is no immediate risk to patients taking [Chantix]***" and [t]here are ***no data available to directly evaluate the carcinogenic potential of [NNV]***." (Exs. 2, 3 (emphasis added).) FDA further recognized that while certain nitrosamines "***may*** increase the risk of cancer if people are exposed to them above acceptable levels ***and over long periods of time***" (*see* Ex. 14 (emphasis added)), Chantix is intended for short-term use only. (Ex. 2.) As a result, FDA repeatedly advised patients to continue taking their recalled Chantix and classified the recall as having only a "remote" chance of "serious adverse health consequences" (*see* Exs. 3, 21, 16). Thus, because Plaintiffs have not alleged how often they used Chantix, let alone plausibly alleged a credible or substantial threat to their health,

Plaintiffs received the benefit of their bargain and cannot base a claim on the purported economic injury of purchasing Chantix that worked and did not harm them.

C. Plaintiffs Cannot Proceed on a Theory That They Would Not Have Purchased Chantix at All Because It Is Worthless.

Plaintiffs' claims also fail because they cannot state a claim simply by asserting that they would not have purchased Chantix absent Pfizer's alleged deception. Here, Plaintiffs do just that. They claim: (a) Pfizer's allegedly deceptive conduct was the sale of an adulterated medication, with an implicit representation that it was not adulterated (CAC ¶ 302); (b) the medication was worthless because it was adulterated; and (c) they would not have purchased an adulterated product. (*Id.* ¶ 231.) Indeed, Plaintiffs assert that absent the purported deception, consumers "would not have been able to purchase the [Chantix] in the first place." (*See, e.g.*, *id.* ¶¶ 24-46.) In other words, Plaintiffs essentially allege that Pfizer's deceptive conduct is their injury.

But courts have been clear that a defendant's allegedly deceptive conduct "cannot be pled 'as both act and injury.'" *Braynina v. TJX Cos.*, 2016 WL 5374134, at *9 (S.D.N.Y. Sept. 26, 2016) (Failla, J.) (quoting *Small v. Lorillard Tobacco Co.*, 720 N.E.2d 892, 898 (N.Y. 1999)). For example, in *Baron*, the plaintiff alleged deceptive practices related to Pfizer's off-label promotion of a medication and, as here, sought a "refund of the purchase price." 42 A.D.3d at 629. The court explained that a plaintiff only has a cognizable injury where "the price of the product was inflated as a result of defendant's deception or that use of the product adversely affected plaintiff's health." *Id.* The court affirmed dismissal because the allegation that "she would not have purchased the drug absent defendant's deceptive practices" was insufficient as a matter of law. *Id.*

Similarly, this Court and others routinely reject an "induced-purchase theory of injury" because plaintiffs must make a "showing of pecuniary or actual harm apart from the deceptive conduct." *Braynina*, 2016 WL 5374134, at *10-11; *see, e.g.*, *Zottola*, 564 F. Supp. 3d at 310

(dismissing for lack of injury where plaintiff alleged putative class members "would not have purchased the Medications if they knew the Medications caused a significantly elevated risk of cancer"); *Dimond*, 2014 WL 3377105, at *9 (dismissing for lack of injury because the "alleged deception—the 18% gratuity—is identical to the pleaded injury. Plaintiff's request for reimbursement of the 18% gratuity underscores this conclusion"). The same result follows here.

D. Plaintiffs' "Alternative" Price Premium Injury Is Implausible.

Plaintiffs originally alleged that the presence of NNV rendered Chantix "worthless" and "they would not have purchased the medication" at all. *See Harris*, 586 F. Supp. 3d at 238. Recognizing that such a theory is not legally viable, Plaintiffs now contend in the "alternative[]" that Chantix is just "worth less" than its price. (CAC ¶¶ 9, 10, 24-46.) Plaintiffs' half-hearted attempt to invoke a price premium theory fails because that theory necessarily requires the availability of lower-priced competitor products that Plaintiffs would have purchased instead of Chantix. A "premium price" is "a price greater than competitors." *Mich. Carpenters' Pension Fund v. Rayonier Advanced Materials, Inc.*, 2019 WL 1429667, at *6 (M.D. Fla. Mar. 29, 2019); *see also Carlson v. Gillette Co.*, 2015 WL 6453147, at *7 (D. Mass. Oct. 23, 2015).

Here, Plaintiffs admit that no competitor products existed when they made their purchases—referring to Chantix as a "first of its kind treatment" (CAC ¶ 3) and that "the FDA . . . granted emergency approval to two other companies' generic versions of Chantix" ***only after*** the recalls (*id.* ¶ 175). Therefore, Plaintiffs cannot plausibly allege that any comparable products were available at the time of their purchases—let alone one free of NNV[8] or that cost less than Chantix and contained a disclosure about nitrosamines such that any price premium allegedly

[8] Even the generic form of varenicline that Plaintiffs tout exceeded FDA's ADI. (*See* Compl ¶ 15 n.9; *see also id.* ¶ 173 n.76.) FDA stated, however, that it would "not object" to Apotex distributing the generic in the U.S. even though it exceeded the FDA's ADI. (Ex. 20.)

assessed could have been due to Pfizer's alleged misstatements. (*See id.* ¶¶ 24-46.)

The Consumer Plaintiffs also cannot plead a price premium "because the prescription drug market is quintessentially inefficient, and thus the relationship between price and value is severed." *Saavedra v. Eli Lilly & Co.*, 2015 WL 9916598, at *1 (C.D. Cal. July 21, 2015). Patients typically are charged only a "co-payment" for Chantix, not the full retail value. (*See, e.g.*, CAC ¶¶ 71, 78, 86, 88.) While the Consumer Plaintiffs here failed to allege the amounts they paid, if any, for their Chantix purchases (*see supra* Part II.A), Ms. Allen previously admitted that she "paid a co-pay for Chantix." *Harris*, 586 F. Supp. 3d at 238. Thus, because the Consumer Plaintiffs cannot plausibly plead that they paid more for Chantix than they would have had Pfizer disclosed the presence of NNV, the price premium theory fails for this independent reason.

III. THE FDCA PREEMPTS CERTAIN OF PLAINTIFFS' CLAIMS.

Federal law impliedly preempts state law "where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013). Impossibility preemption exists when the defendant could not "independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623. Federal law also impliedly preempts any attempt to enforce the FDCA, because the FDCA "leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with" its substantive provisions. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Here, the FDCA preempts: (1) Plaintiffs' claims premised on Pfizer's failure to disclose the presence of NNV in the Chantix label, because Pfizer could not unilaterally change Chantix's label without FDA's prior approval; (2) Plaintiffs' claims premised

on NNV caused by an FDA-approved excipient, because Pfizer could not unilaterally change the excipient without FDA's prior approval; and (3) any claims based solely on Pfizer's alleged violations of cGMP regulations and provisions of the FDCA pertaining to adulteration.

A. The FDCA Preempts Plaintiffs' Claims That Pfizer Failed to Disclose NNV.

To state a claim for failure to warn "that is not preempted by the FDCA, a plaintiff must plead 'a labeling deficiency that [defendant] could have corrected using the CBE [Changes Being Effected] regulation.'" *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707-08 (2d Cir. 2019). Under the CBE regulation, "a manufacturer may only change a drug label [after FDA approval]" to "add or strengthen a contraindication, warning, precaution or adverse reaction" in light of "sufficient 'evidence of a causal association'" based on "newly acquired information." *Utts*, 226 F. Supp. 3d at 177-78; *see Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019) ("manufacturers cannot propose a change [under the CBE regulation] that is not based on reasonable evidence" of a causal association). Newly acquired information is defined as information not previously submitted to the FDA that "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to the FDA.'" 21 CFR § 314.3(b).

"[N]ewly acquired information 'must provide *reasonable evidence* of a causal association of a clinically significant adverse reaction,'" which "'has a significant impact on therapeutic decision-making, such as a risk that is potentially fatal or otherwise serious.'" *McGrath v. Bayer Healthcare Pharms. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019) (emphasis in original). "The FDA imposes this standard because it 'recognizes that exaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug . . . [and] theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance.'" *Id.* In *McGrath*, the plaintiff's failure to warn claims were preempted because the plaintiff had not plausibly pled the requisite "causal association." 393 F. Supp. 3d at

168. There, the purported newly acquired information was "inconclusive" and the potential for toxicity was still "unknown." *Id.* at 169. The court held that the plaintiff "must plead more than the mere possibility" that the medication could cause the adverse reaction, which the plaintiff had failed to do. *Id.* at 168; *see also Gibbons*, 919 F.3d at 709 (affirming dismissal of 15 actions because "Plaintiffs' complaints lack[ed] sufficient factual allegations" of newly acquired information to "state a claim that is not preempted"); *Gayle v. Pfizer, Inc.*, 452 F. Supp. 3d 78, 87 (S.D.N.Y. 2020) (claims preempted because plaintiffs had not alleged manufacturer had "newly acquired information").

Here, Plaintiffs repeatedly allege Pfizer "omitted" the presence of NNV in the Chantix label. (*See, e.g.*, CAC ¶¶ 274, 302.) But Plaintiffs do not allege Pfizer was in possession of newly acquired information constituting reasonable evidence of a causal association to justify a label change under the CBE regulation. "On the contrary, in announcing the recall, the FDA stated that there was 'no immediate risk'" to patients taking Chantix," *Harris*, 586 F. Supp. 3d at 245, "*no data* available to directly evaluate the carcinogenic potential of [NNV]" (Ex. 3 (emphasis added)), and only a "*remote*" chance of serious health consequences. (Exs. 21, 16 (emphasis added).) This is the exact type of "theoretical" or "speculative" risk that FDA has cautioned against, and courts have found insufficient to avoid preemption. Moreover, Plaintiffs do not allege that Pfizer had reasonable evidence of a causal association between the presence of NNV in Chantix and cancer (especially compared to smokers' use of tobacco-specific nitrosamine-laden cigarettes). Plaintiffs also fail to meet their burden under *Gibbons* to "plead a labeling deficiency that [Defendants] could have corrected using the CBE regulation" because the CAC is devoid of allegations of when the Consumer Plaintiffs purchased Chantix (*see supra* p. 8), and thus they fail to plead that significant adverse risk information was revealed to Pfizer *before* their purchases. Thus, Plaintiffs' claims

premised on Pfizer's alleged failure to disclose the presence of NNV are preempted.

B. Claims Premised on Chantix's Misbranding Due to an FDA-Approved Excipient Are Preempted.

"A drug is misbranded if . . . it is 'dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed . . . in the labeling thereof.'" *Utts*, 226 F. Supp. 3d at 177 (quoting 21 U.S.C. § 352(j)). "[A] manufacturer must obtain prior FDA approval for any 'major' changes to the design and manufacturing of already-approved drug products, but not for 'moderate' or 'minor' changes." *Ignacuinos v. Boehringer Ingelheim Pharms. Inc*, 8 F.4th 98, 101 (2d Cir. 2021) (quoting 21 CFR § 314.70). Major changes include "changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved NDA.'" *Utts*, 226 F. Supp. 3d at 186 (quoting 21 CFR § 314.70(b)(2)(i)).

In *Polson v. Astrazeneca Limited Partnership*, the court denied the plaintiff leave to amend as futile where the plaintiff sought to hold the defendant "liable for a perceived defect with the drug's design, formulation, and composition," because such claims are preempted. 2023 WL 2770687, at *3 (D. Conn. Apr. 4, 2023). When "state product liability law requires a drug manufacturer to alter the drug's formulation, but federal law requires those changes to be approved by the FDA, the state law must give way to the federal law." *Id.*; *see also Utts*, 226 F. Supp. 3d at 185-86 (preempting design defect claims); *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015) (same); *Epstein v. Gilead Scis., Inc.*, 2020 WL 4333011, at *2 (S.D. Fla. July 27, 2020) (same).

Here, Plaintiffs repeatedly assert that Chantix was unsafe due to the presence of NNV. (CAC ¶ 198, *see also id.* ¶¶ 8-9, 24-46.) To the extent those claims would have required Pfizer to use an excipient other than its FDA-approved excipient (Ex. 17 at 2), the claims are preempted since "[t]he complaint's allegations of harm" go "to the nature of the composition of the drug."

Utts, 226 F. Supp. 3d at 186. Similarly, while Plaintiffs allege that Chantix "never should have been offered to consumers in the first place" (CAC ¶ 337), "such claims have been explicitly repudiated by the Supreme Court." *Utts*, 226 F. Supp. 3d at 186 (rejecting contention "that the defendants should never have sold the FDA-approved formulation" as preempted).

C. Claims Premised on Pfizer's Alleged Violations of cGMP Regulations Are Impliedly Preempted.

Finally, to the extent Plaintiffs' claims are based on Pfizer's alleged cGMP violations or the FDCA's prohibitions on adulteration, the FDCA does not "create a private cause of action," and Plaintiffs, like those in *Harris*, have disclaimed "any attempt to privately enforce the FDA's limits on nitrosamine contamination." *Compare* 586 F. Supp. 3d at 239 *with* CAC ¶ 133. Similarly, to the extent Plaintiffs' claims are based on an assertion that the mere sale of an FDA-approved medication necessarily implies its sameness, active ingredient, or cGMP compliance, that finds no support in the law and would be preempted in any event. *See Anthony v. Country Life Mfg., L.L.C.*, 2002 WL 31269621, at *2-3 (N.D. Ill. Oct. 9, 2002) (holding "mere act" of "producing and marketing adulterated food" did not constitute violation of Illinois Consumer Fraud Act and claim that product "contain[ed] ingredients that the FDA had not approved" was "preempted by the FDCA"), *aff'd* 70 F. App'x 379 (7th Cir. 2003). In *Buckman*, the Supreme Court held that state law claims that "exist solely by virtue of the FDCA . . . requirements" are impliedly preempted. 531 U.S. at 353. Applying *Buckman*, courts have repeatedly held that claims based on conduct that allegedly "violate[] the FDA's CGMPs" are "impliedly preempted." *See, e.g., Frere v. Medtronic, Inc.*, 2016 WL 1533524, at *7 (C.D. Cal. Apr. 6, 2016); *Ebrahimi v. Mentor Worldwide LLC*, 2017 WL 4128976, at *6 (C.D. Cal. Sept. 15, 2017) (finding manufacturing defect claim preempted because it "hinges entirely on conduct [plaintiff] claims violates the FDCA as well as the FDA's [cGMPs]").

Likewise, in *Loreto v. Procter & Gamble Co.*, the Sixth Circuit affirmed dismissal under *Buckman* where the plaintiff's theory was that the defendant "omitted telling consumers that its products were 'illegal.'" 515 F. App'x 576, 579 (6th Cir. 2013). The court held that the "theory of liability depend[ed] entirely upon an FDCA violation," explaining that "the *only* reason [defendant's] products were allegedly 'illegal' was because they failed to comply with FDCA labeling requirements." *Id.*; *see also Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1050 (9th Cir. 2022); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (to avoid preemption, plaintiff must rely on "traditional state tort law causes of action that predated the federal enactments, and did not implicate a duty owed to the FDA"). Because the FDCA lacks a private right of action, Plaintiffs "cannot rely on it for purposes of asserting a state-law consumer claim under" the NYGBL or other consumer fraud statutes. *Verzani v. Costco Wholesale Corp.*, 2010 WL 3911499, at *3 (S.D.N.Y. Sept. 28, 2010), *aff'd*, 432 F. App'x 29 (2d Cir. 2011); *see also Anthony*, 2002 WL 31269621, at *3 (Illinois Consumer Fraud Act claim "that defendant sold nutrition bars containing ingredients that the FDA had not approved" preempted by FDCA). The same applies here.

IV. PLAINTIFFS' TORT CLAIMS ARE BARRED BY THE ECONOMIC LOSS DOCTRINE.

Plaintiffs' negligent misrepresentation, negligence, and negligence per se claims are all barred by the economic loss doctrine. "The economic loss doctrine seeks to preserve the role of contract and warranty law by precluding tort liability where a product causes only monetary harm." *Rochester-Genesee* Reg'l Trans. Auth. v. Cummins Inc., 2010 WL 2998768, at *8 (W.D.N.Y. July 28, 2010). Thus, "[t]he Second Circuit has dismissed tort liability claims under the economic loss doctrine, even when actions for breach of contract and warranty were also dismissed." See Miramontes v. Ralph Lauren Corp., 2023 WL 3293424, at *14 (S.D.N.Y. May 5, 2023). As Judge

Cote already held, "[b]ecause the plaintiffs claim only economic harm, rather than personal injury, the economic loss doctrine bars their negligent misrepresentation claim." Harris, 586 F. Supp. 3d at 243. The same applies to the newly-asserted negligence and negligence per se claims here as outlined in Appendix A. See Appendix A at 13-16.

The economic loss doctrine also bars Plaintiffs' fraud claims in ten jurisdictions and Plaintiffs' fraudulent omission and concealment claims are barred in five jurisdictions as outlined in Appendix A. *See id.* at 16-17.

V. PLAINTIFFS DO NOT HAVE ARTICLE III STANDING FOR A NATIONWIDE CLASS OR INJUNCTIVE RELIEF.

At an "irreducible constitutional minimum," Article III requires Plaintiffs to show they have ***personally suffered*** some actual or threatened injury due to Pfizer's conduct and that the injury is "fairly traceable" to the challenged action" and is "likely . . . [to be] redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Plaintiffs do not have standing to: (a) assert claims under laws of states where the Consumer Plaintiffs or the TPP's insureds did not fill their prescriptions; or (b) seek injunctive relief.

A. Plaintiffs Lack Standing to Assert Claims Under the Laws of States Where They or Their Insureds Did Not Fill Their Prescriptions.

Consumer Plaintiffs, who are residents of only twelve states, cannot pursue a nationwide class asserting violations of state consumer protection laws beyond where they themselves filled their prescriptions. (*See* CAC ¶ 205.) In *Miramontes v. Ralph Lauren Corp.*, the court rejected the plaintiff's attempt to assert a class action under the laws of "18 states" as "her . . . transaction took place in Texas" and the "state consumer protection laws invoked by Plaintiff . . . are presumed to be territorial in nature." 2023 WL 3293424, at *7-8. Here, Consumer Plaintiffs can only seek to represent putative classes consisting of their own states' residents. Similarly, the

TPPs also do not have standing to assert claims under the laws of 14 states and the District of Columbia where they are not located and where their members did not purchase medication.[9]

B. Plaintiffs Lack Standing to Seek Injunctive Relief.

Plaintiffs' request for injunctive relief (CAC Prayer for Relief) also fails because they have not alleged a risk of future harm. "Past injuries . . . do not confer standing to seek injunctive relief unless the plaintiff can demonstrate that [s]he is likely to be harmed again in the future in a similar way." *Kommer v. Bayer Consumer Health*, 710 F. App'x 43, 44 (2d Cir. 2018) (*quoting Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 238-39 (2d Cir. 2016)). Plaintiffs have not done so here.

Regardless, Plaintiffs cannot demonstrate standing for injunctive relief because they are already aware of the purported NNV and thus cannot be misled in the future. *See, e.g.*, *Nguyen v. Algenist LLC*, 2022 WL 17251733, at *4 (S.D.N.Y. Nov. 28, 2022) (Failla, J.) (once plaintiffs know the truth they "cannot be misled"). And, Pfizer voluntarily recalled all lots of Chantix, so there is nothing to enjoin. *Nicosia*, 834 F.3d at 239 (dismissing injunctive relief because Amazon stopped sales). Thus, Plaintiffs' request for injunctive relief must be dismissed.

VI. *RES JUSDICATA* BARS PLAINTIFF MARY ALLEN'S CLAIMS.

Res judicata "bars a plaintiff from relitigating claims . . . that [she] lost in a previous action against the same defendant and claims that the plaintiff could have brought in that earlier action but did not." *He v. United States*, 2023 WL 3045516, at *2 (S.D.N.Y. Apr. 21, 2023) (Failla, J.). "[T]he doctrine bars 'later litigation if [an] earlier decision was [i] a final judgment on the merits, [ii] by a court of competent jurisdiction, [iii] in a case involving the same parties or their privies,

[9] *See, e.g.*, *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 151-58 (E.D. Pa. 2009) (dismissing claims under 40 jurisdictions' laws where third-party payors did not allege to have purchased or made reimbursements for prescription drug); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 758 (E.D. Pa. 2014) (14 jurisdictions); *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 692-94 (E.D. Pa. 2014) (32 jurisdictions); *In re Propranolol Antitrust Litig.*, 249 F. Supp. 3d 712, 726 (S.D.N.Y. 2017) (13 jurisdictions).

and [iv] involving the same cause of action.'" *Cho v. Seventh Ave. Fine Foods*, 2016 WL 1717214, at *3 (S.D.N.Y. Apr. 28, 2016) (Failla, J.) (internal quotation omitted). Each element is met here.

First, the *Harris* dismissal was a final judgment on the merits because "a Rule 12(b)(6) dismissal is deemed to be a judgment on the merits.'" *Overview Books, LLC v. United States*, 755 F. Supp. 2d 409, 415-16 (E.D.N.Y. 2010), *aff'd*, 438 F. App'x 31 (2d Cir. 2011). Second, *Harris* was a court of competent jurisdiction with "jurisdiction pursuant to the Class Action Fairness Act of 2005." 586 F. Supp. 3d at 238. Third, there is no dispute that both Ms. Allen and Pfizer were parties in *Harris*. Finally, this action involves the same Chantix purchases litigated in *Harris*, 586 F. Supp. 3d at 238-39, and *res judicata* applies even where a later action "is based on different legal theories or seeks dissimilar or additional relief." *See Simmtech Co. v. Citibank, N.A.*, 2016 WL 4184296, at *7 (S.D.N.Y. Aug. 3, 2016). Accordingly, Ms. Allen's claims are barred.

VII. PLAINTIFFS' CLAIMS FAIL FOR ADDITIONAL REASONS.

Plaintiffs' claims also fail for additional claim-specific reasons as outlined below.

A. Plaintiffs' Fraud Claims Fail to Plausibly Plead Any Fraudulent Intent.

Plaintiffs' fraud claims fail for the additional reason that they do not allege fraudulent intent. As Judge Cote held, Plaintiffs have not alleged sufficient facts "to give rise to a 'strong inference'" of fraudulent intent because they have not alleged that "Pfizer knew or believed that Chantix was actually contaminated, particularly when plaintiffs purchased Chantix." 586 F. Supp. 3d at 241; *see also Phoenix Cos. v. Concentrix Ins. Admin. Solutions Corp.*, 554 F. Supp. 3d 568, 601 (S.D.N.Y.) (Failla, J.) ("conclusory and speculative allegations . . . do not give rise to a strong inference of fraudulent intent"). This holding applies here too.

Plaintiffs do not allege that Pfizer ***actually knew*** about the NNV in Chantix at the time of their purchases (the dates of which are unknown), let alone that Pfizer ***intended to withhold*** such information from Plaintiffs. Instead, they assert the same allegations rejected as insufficient in

Harris—that Health Canada requested an investigation into NNV in October 2020 and ***other*** drug manufacturers found ***other*** nitrosamines in their medications years before. (*See* CAC ¶ 267.) These allegations are insufficient to establish an inference of fraudulent intent by Pfizer. *See supra* Part I.B.

B. Plaintiffs' Warranty Claims Fail to Allege Essential Elements of Each Claim.

Plaintiffs' warranty claims fail for several additional reasons. First, "the presence of nitrosamines does not provide a basis for a breach of express warranty claim" and, thus, Plaintiffs do not plausibly allege that Pfizer breached "any affirmation, promise, or description" related to Chantix. *See Harris*, 586 F. Supp. 3d at 244.

Second, Plaintiffs' express and implied warranty claims fail because they do not allege privity. The Consumer Plaintiffs' skeletal allegations elide from whom they purchased Chantix, but it is reasonable to assume that they purchased from a third-party retailer like "a pharmacy" as alleged in *Harris* by plaintiff Mary Allen. (CAC ¶¶ 24-46.)[10] Likewise, in alleging that they "reimburs[ed]" their "beneficiaries' purchases of prescription drugs" (*Id.* ¶¶ 48, 72, 75), the TPPs cannot allege that they purchased Chantix from Pfizer either.[11]

Third, Plaintiffs' express and implied warranty claims fail in 37 jurisdictions as outlined in Appendix A (at 5-7) because they do not allege pre-suit notice. *See, e.g.*, *Colella*, 348 F. Supp. 3d at 144 (dismissing warranty claim because plaintiff "makes no allegations and states no facts showing that notice was provided to defendant"). Here, Plaintiffs' allegations for both their express and implied warranty claims fail to allege that they provided the requisite notice. (*See* CAC ¶¶ 218-33 (express warranties); *id.* ¶¶ 234-56 (implied warranty).)

[10] Nine jurisdictions in which the Consumer Plaintiffs reside require privity. *See* Appendix A at 1-4.

[11] 24 jurisdictions require privity for implied warranty and 21 for express warranty. *See* Appendix A at 1-4.

Fourth, Plaintiffs' implied warranty of merchantability claim fails because the CAC "does not allege that Chantix failed to fulfill its purpose" of helping smokers quit, nor does it allege that NNV "harmed plaintiffs, or even put them at significant risk." *Harris*, 586 F. Supp. 3d at 245.

Finally, the TPPs' warranty claims fail because "[t]he remedy for a breach of warranty, whether express, implied, or of fitness for a particular purpose, belongs solely to a ***buyer*** of the goods," and "[p]aying for part of the cost of something is not the same as buying it." *In re Rezulin Prod. Liab. Litig.*, 390 F. Supp. 2d 319, 331-34 (S.D.N.Y. 2005) (emphasis added) (dismissing claims under 26 jurisdictions); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 84 (D. Mass. 2007) ("[T]he plaintiffs are TPPs who do not buy a product, but rather reimburse for it.").

C. Plaintiffs' Magnuson Moss Warranty Act Claim Fails for Multiple Reasons.

Plaintiffs' Magnuson Moss Warranty Act ("MMWA") claim fails for three independent reasons. First, to state a claim under the MMWA, a plaintiff must adequately plead "a state law violation of either an express or implied warranty." *Meserole v. Sony Corp. of Am., Inc.*, 2009 WL 1403933, at *10 (S.D.N.Y. May 19, 2009). Because Plaintiffs fail to allege a breach of express or implied warranty under state law (*see supra* Part VII.B), their "derivative" MMWA claim fails too. *See, e.g.*, *Gordon v. Target Corp.*, 2022 WL 836773, at *15 n.8 (S.D.N.Y. Mar. 18, 2022).

Second, "the alleged misrepresentation is governed by the FDCA and is not actionable under the MMWA." *Mahoney v. Endo Health Solutions, Inc.*, 2016 WL 3951185, at *8-9 (S.D.N.Y. July 20, 2016); *see also Hernandez v. Johnson & Johnson Consumer, Inc.*, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (collecting cases and explaining that the "'majority of courts . . . have concluded that [the] MMWA claim is barred'" for products governed by the FDCA) (internal quotation omitted). Because Chantix is an "FDA-approved" prescription medicine (*see* CAC ¶ 115), "the MMWA is inapplicable." *Hernandez*, 2020 WL 2537633, at *5.

Third, Plaintiffs' MMWA claim fails because the brand name "Chantix" is not a written warranty as it does not promise that the product "is defect free or will meet a specified level of performance over a specified period of time." *Kamara v. Pepperidge Farm, Inc.*, 570 F. Supp. 3d 69, 81 (S.D.N.Y. 2021); *cf. Harris*, 586 F. Supp. 3d at 244 ("Chantix is itself a brand name drug. Its name therefore confers no warranty that it is identical to anything except itself.").

D. Plaintiffs' Consumer Protection Claims Fail for Multiple Reasons.

Plaintiffs' consumer protection claims fail for several independent reasons. Preliminarily, Plaintiffs cannot assert claims under the law of six jurisdictions because those states' consumer protection statutes bar class actions.[12] In addition, Plaintiffs fail to allege that they sent a pre-suit demand for relief, as required by ten jurisdictions.[13] Moreover, Plaintiffs cannot bring claims under the law of Puerto Rico (*see* CAC ¶ 314ccc), which "does not provide for a private right of action for consumer fraud." *In re Vioxx Prod. Liab. Litig.*, 522 F. Supp. 2d 799, 810 (E.D. La. 2007) (citing *Simonet v. SmithKline Beecham Corp.*, 506 F. Supp. 2d 77, 90-91 (D.P.R. 2007)).

In addition, Plaintiffs claims also fail under New York law because Plaintiffs have not demonstrated, and cannot demonstrate, that Pfizer engaged in the requisite consumer-oriented conduct because Chantix must be prescribed by a doctor. *See, e.g.*, *Wholey v. Amgen, Inc.*, 165 A.D.3d 458, 458 (N.Y. App. Div. 2018) (dismissing NYGBL claims against a pharmaceutical manufacturer "because the generally alleged deceptive practice of failing to provide adequate warnings by concealing information is, as a matter of law, not a practice directed at consumers"); *see also Amos v. Biogen Inc.*, 28 F. Supp. 3d 164, 174 (W.D.N.Y. 2014) (dismissing NYGBL claim because a manufacturer's warning to a doctor of a medicine's risks "is not a 'consumer

[12] Ga. Code Ann. § 10-1-399(a); La. Stat. Ann. § 51:1409(A); Miss. Code. Ann. § 75-24-15(4); Mont. Code Ann. § 30-14-133(1)(a); S.C. Code Ann. § 39-5-140(a); Tenn. Code Ann. § 47-18-109(a)(1), (g).

[13] *See* Appendix A at 1.

oriented' act"); *Zottola*, 564 F. Supp. 3d, at *310 (same).

Similarly, TPPs' consumer protection claims fail in at least 9 jurisdictions because they are either not considered a "consumer"[14] or did not buy a product for "primarily for personal, family, or household purposes."[15] In addition, TPPs cannot assert claims under the consumer protection statutes of states that have not repudiated *Illinois Brick*'s prohibition against indirect purchaser damages actions.[16]

E. Plaintiffs' unjust Enrichment Claims Are Duplicative, Cannot Constitute an Independent Cause of Action, and Fail for Other Reasons.

Plaintiffs' unjust enrichment claims fail for several reasons. First, the Court in *Harris* dismissed plaintiffs' unjust enrichment claims as duplicative because plaintiffs had not "explain[ed] why their unjust enrichment claim [was] distinct from their other claims." 586 F. Supp. 3d at 246. The Court should do so again here in 25 jurisdictions, *see* Appendix A at 9-11, as the unjust enrichment claim is premised on the same allegations as the other claims—that

[14] *See, e.g.*, *MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, 2019 WL 1418129, at *18 (D.N.J. Mar. 29, 2019) ("Third-party payors are not considered consumers under the NJCFA.'") (quoting *Cent. Reg'l Empls. Benefit Fund v. Cephalon, Inc.*, 2009 WL 3245485, at *3 (D.N.J. Oct. 7, 2009)); *In re Dram Antitrust Litig.*, 516 F. Supp. 2d 1072, 1116, 1119 n.12 (N.D. Cal. 2007) (dismissing consumer protections claims under Rhode Island and West Virginia law because those jurisdictions define "consumers" as "natural persons"); *In re Aggrenox Antitrust Litig.*, 2016 U.S. Dist. LEXIS 104647, at *38 (D. Conn. Aug. 9, 2016) (noting that the "definition of 'consumer'" under Vermont law "allows businesses to sue as consumers with respect to the products that they use as consumers," but a TPP's purchase or reimbursement "for consumer products that its members use, does not make Humana a consumer of those products"); *Cannon v. Wells Fargo Bank, N.A.*, 926 F. Supp. 2d 152, 172 (D.D.C. 2013) (D.C. Consumer Protection Procedures Act "applies only to consumer-merchant relationships"); *S. Ill. Laborers' & Emps. Health & Welfare Fund v. Pfizer Inc.*, 2009 WL 3151807, at *9-10 n.18 (S.D.N.Y. Sept. 30, 2009) (dismissing third-party payor claims under New Jersey, Ohio, and Texas law).

[15] *See, e.g.*, *In re Pharma. Indus. Average Wholesale Price Litig.*, 252 F.R.D. 83, 97 n.13 (D. Mass. 2008) ("Michigan does not provide a cause of action when an item is purchased primarily for business or commercial purposes."); *In re Lidoderm Antitrust Litig.*, 103 F. Supp. 3d 1155, 1164-65 (N.D. Cal. 2015) (holding that a TPP was not a consumer under the consumer protection statutes of the District of Columbia and Montana).

[16] *See, e.g.*, *Abbott Labs., Inc. v. Segura*, 907 S.W.2d 503, 505-06 (Tex. 1995) (holding indirect purchasers do not have standing under Texas Deceptive Trade Practices-Consumer Protection Act and noting that the court was persuaded by "the reasoning of *Illinois Brick*"); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 544 (E.D. Pa. 2010) ("Indirect purchaser class actions are precluded under . . . the [Illinois Consumer Fraud Act]."); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 763 (E.D. Pa. 2014) ("The end-payor plaintiffs cite no authority for the proposition that indirect purchasers may bring an antitrust or consumer-protection claim under the laws of Colorado, Delaware, Georgia, Kentucky, Pennsylvania, South Carolina, Texas, or Virginia.").

Chantix was "illegal" to sell. (CAC ¶ 379.)

Second, Plaintiffs' unjust enrichment claims fail under California and Texas law, which do not recognize such a cause of action. *See Wilber v. Top Glob. Cap., Inc.*, 2014 WL 12594138, at *4 (C.D. Cal. Nov. 4, 2014) ("Unjust enrichment is . . . not a separate cause of action"); *Midwestern Cattle Mktg., L.L.C. v. Legend Bank, N.A.*, 999 F.3d 970, 972 (5th Cir. 2021) ("[U]njust enrichment" is "not a distinct cause of action").

Third, the claims brought under 26 jurisdictions' laws also fail because Plaintiffs do not allege that they conferred a direct benefit on Pfizer as the Consumer Plaintiffs likely purchased Chantix from a third-party retailer like "a pharmacy" and where TPPs "reimburs[ed]" their "beneficiaries' purchases of prescription drugs" (CAC ¶¶ 48, 72, 75). *See, e.g., Alin v. Am. Honda Motor Co.*, 2010 WL 1372308, at *15 (D.N.J. Mar. 31, 2010) (A "benefit conferred upon a retailer not sharing in profits with the product manufacturer ***does not result*** in the manufacturer's unjust enrichment.") (emphasis added).[17]

CONCLUSION

For the reasons stated above, Pfizer respectfully requests that the Court dismiss Plaintiffs' CAC in its entirety and with prejudice.[18]

[17] *See* Appendix A at 7-9. Similarly, TPPs cannot use unjust enrichment as an end run around *Illinois Brick* in 16 jurisdictions (*see id.* at 11-13) because the "vast majority of courts have held that indirect purchasers may not bring state claims for unjust enrichment if they otherwise would be barred from bringing a claim under that state's antitrust and consumer-protection statutes." *In re Novartis & Par Antitrust Litig.*, 2019 WL 3841711, at *6 (S.D.N.Y. Aug. 15, 2019).

[18] Where, as here, a plaintiff is "aware of the deficiencies in his complaint when he first amended, he clearly has no right to a second amendment" and "a busy district court need not allow itself to be imposed upon by the presentation of theories seriatim." *See Jones v. Cuomo*, 542 F. Supp. 3d 207, 226 (S.D.N.Y. 2021) (Failla, J.).

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Respectfully submitted,

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